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Subject: Comments and Recommendations for LCB File No. R004-14P

I attended today's Medical Marijuana Stakeholders Meeting via videoconference on the web, but was unable to make comments in that format. This letter contains my comments relative to Section 120 of the subject regulation. Specifically, I will address a potential problem related to Section 120 that will create confusion for cultivators, testing labs and the enforcers.

I will preface my comments by briefly pointing out that my career involved quality control procedure drafting and enforcement for Boeing and GE. In short, I have considerable experience with the drafting of procedures related to quality control, and it is based on that experience that I see a problem with Section 120 as currently drafted. I also am a Nevada medical marijuana card holder.

The regulations as currently drafted ignore marijuana strains and varieties when defining batches, instead relying on temporal proximity which does not correlate with actual cultivation practice. This is a key oversight. Strains and varieties are how the cultivators, dispensaries and patients organize marijuana and the regulation should take that into account. Major strains are Sativa, Indica and Afghanica, and hybrids of the strains are common. Major varieties are Kush, Sour Diesel, Cheese, Skunk and Girl Scout Cookie. Strains and varieties are known to differ widely in THC and CBD levels, and there numerous varieties.

Sections 2 and 3 define batch and batch number. In brief, a batch means marijuana planted and harvested at the same time. Section 120 states, "...a cultivation facility shall segregate all harvested marijuana into homogenized batches and select a random sample from each batch for testing by an independent testing laboratory." As indicated, these definitions do not take the marijuana plant biology into account, and ignore how marijuana production is typically organized.

The intent of Section 120 is clear relative to having a representative sample for the testing lab, but the problem arises from the loose definition of batch. As drafted, the regulation would allow different strains and varieties planted and harvested at the same time to be considered a batch. The result of such homogenized batches would be that a single random sample would not in any way be representative of the variation present in that batch. In fact, the sample would not in any sense

represent the average THC or CBD concentrations of the homogenous batch. For example, the random sample could consist of a single strain and variety, or a mix of several strains and varieties. The consequence would be that the medication label based on the testing lab results could seriously misrepresent the actual levels of THC and CBD and other ingredients in the batch. This suggests, as far as the marijuana potency is concerned, that the test results were not from a homogenous batch. The term homogenous batch is never used in quality control to define such a mix of different things. Homogenous should mean homogenous---that the content is intended to have similar properties or qualities, not be a blend or mix of markedly differing things like strains and varieties. As an example, a homogenous batch of fasteners at Boeing would never consist of fasteners with differing lengths, diameters, materials and finishes. The things in a homogenous batch have to be similar on their key attributes. Regarding the regulation, those key attributes are the potency (%THC, %CBD) and the other test factors outlined in the regulation.

In addition to the testing lab test results from homogenized batches providing potentially misleading results, the regulation does not take into account that medical marijuana patients and the dispensaries go by strains and varieties. Patients will ask for specific strains and varieties, so that information should be included in the definition of a batch and batch number.

To provide greater transparency, and to ensure the testing lab results correspond to how the patients actually purchase medication, the batch numbers should include the following five details:

Strain: (1) Sativa, (2) Indica, (3) Ruderalis, (4) Afghanica, (5) Hybrid
Variety: variety name
Plant Date: MMDD
Harvest Date: MMDD
Unique identifier used by cultivator

For example, the batch number **Hybrid_Bubba Kush_0915_1118_B14007**
uniquely identifies the plants planted on 09/15/14 and harvested on 11/18/14 that were a hybrid strain of Bubba Kush. The advantage to this approach is that batches are more clearly defined. This will benefit the cultivator, the testing lab, the patients and the regulators. The B14007 was invented to indicate the batch was the cultivators 7th batch in 2014. This approach also would ensure test results based on homogenized batches would better align with the actual properties of the medication tested. In addition, batch numbers provide the plant and harvest dates, which can be useful information.

The definition of homogenized batches also requires greater clarity. With batches defined as suggested above, a homogenous batch would consist of marijuana plants from the same strain, variety, planting and harvesting times. Thus, a random sample of the marijuana in such a homogenized batch would be truly representative of the medication's properties. That is, the homogenized batch would consist of plants intended to have similar qualities and properties.

In my opinion, Section 120 also requires more clarity in defining how random samples are to be pulled from homogenized batches. My experience in industry is that unless such procedures are in-place and regularly audited, those whose duties are to pull a random sample will often simply pull what is known as a convenience sample, that is, grab the first thing they see. Or even worse, they will purposely try to stack the test results by pulling a non-representative sample. There are well known quality control sampling methods available and those should be provided as guidance for how to pull a random and representative sample of a homogenized batch. I cannot overstate how critical it is that samples pulled for the testing labs be random and representative of the homogenized batch. As an example of such a procedure, consider the following:

> *Procedure 420: How to Pull the Testing Lab Sample*
> *As defined in Section 120 (and the cultivators internal quality procedures), combine all the marijuana buds that meet the definition of a homogenous batch into a large container. Gently rotate the homogenous batch container for a minimum of 10 minutes to ensure blending of the various plant buds. Open the homogenous batch container and pull the required sample size to be sent to the testing lab.*

This approach ensures the sample is indeed random and that the test results are as representative of the marijuana in the homogenous batch as possible. The cultivators must be required to clearly define the procedure by how samples are assured to be random and representative and those procedures can be audited, as well as how the procedures are being followed.

The short version of this letter goes like this: The current definition of batch would allow the marijuana included in a homogenous batch to consist of widely differing strains and varieties, all known to differ markedly in their active ingredient levels, specifically THC and CBD. By adding additional details to the definition of batch and homogenized batch, the patients would have greater assurance that the testing lab results provided on the medication label accurately reflect the medication's properties.

In closing, I want to thank you Marla personally for the outstanding job you and your team have done drafting these detailed regulations. I hope my observations and suggestions serve to improve the final regulation. I am confident Nevada's medical marijuana regulations will be the best in the country.

Victor N. Morin, Ph.D.

Appendices

(A)

PROPOSED REGULATION OF THE DIVISION OF PUBLIC AND BEHAVIORAL HEALTH

OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES LCB File No. R004-14

February 11, 2014

Sec. 2. "Batch" means a specific lot of marijuana grown from one or more seeds or cuttings that are planted and harvested at the same time.

Sec. 3. "Batch number" means a unique numeric or alphanumeric identifier assigned to a batch by a medical marijuana establishment when the batch is planted.

(B)

DISCUSSION POINTS CONCERNING LABORATORIES MARIJUANA TESTING
February 24, 2014

Section 120:
Subsection 1 of this section specifies that before packaging raw marijuana for sale, a cultivation facility shall segregate all harvested marijuana into homogenized batches and select a random sample from each batch for testing by an independent testing laboratory. The lab is responsible for collecting the samples unless the lab agrees that a cultivation 2 facility representative may collect the sample. The key to this subsection is that the lab is responsible for ensuring the sample is representative.